# Title 16, Division 4. Board of Chiropractic Examiners.

NOTICE IS HEREBY GIVEN that the Board of Chiropractic Examiners (hereafter "Board") is proposing to add regulations described in the Informative Digest below. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or email to the address listed under <u>Contact Person</u> in this Notice, must be received by the Board of Chiropractic Examiners at its office no later than 5:00 p.m. on July 1, 2013.

The Board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office no later than 15 days before the close of the written comment period.

The board, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by sections 1000-4(b) and 1000-10 of the Business and Professions Code (Chiropractic Initiative Act of California Stats. 1923 p. 1xxxviii); and to implement, interpret or make specific sections 1000-4(b), 1000-7and 1000-10 of the Business and Professions Code (Chiropractic Initiative Act of California Stats. 1923 p. 1xxxviii); the board is considering changes to Title 16, Division 4, Article 2 of the California Code of Regulations as follows:

# INFORMATIVE DIGEST/ POLICY STATEMENT OVERVIEW

The Chiropractic Initiative Act Section 1000 - 4(b) authorizes the board to adopt regulations as they may deem proper and necessary for the performance of its work, the effective enforcement and administration of this act, the establishment of educational requirements for license renewal, and the protection of the public.

This proposal would establish a standard of care or procedures under which Extracorporeal Shock Wave Therapy involving the use of anesthesia or anesthetic may be performed by chiropractors and establish enforcement authority for the Board to discipline licensees who fail to comply with this proposal. This proposal will promote consumer protection by clearly defining the scope of the health care

practitioners' role during this therapy and limiting the type of technology which may be used.

The Board is proposing to make the following changes:

# 1. Add Section 318.2(a).

This proposal would add section 318.2(a) to define the type of facility in which ECSW therapy involving anesthesia or anesthetic may be performed as a hospital that is licensed by the California Department of Public Health, Licensing and Certification Program or and ambulatory surgery center that is licensed by the California Department of Public Health, Licensing and Certification Program, operating pursuant to section 1248.1 of the Health and Safety Code or accredited by an agency approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and Safety Code (commencing with section 1248).

# 2. Add section 318.2(b).

This proposal would add section 318.2(b) to prohibit the provision of ECSW therapy involving anesthesia or anesthetic in a mobile van as defined in subdivision (h) of section 1248.1 of the Health and Safety Code.

## 3. Add section 318.2(c).

This proposal would add section 318.2(c) identify and authorize physicians and surgeons or other California licensed health care providers authorized under California law to administer anesthesia as the only person who shall administer anesthesia to patients during ECSW therapy under anesthesia.

#### 4. Add Section 318.2(d).

This proposal would add section 318.2(d) to require a patient to undergo an examination by a California licensed physician and surgeon prior to receiving ECSW therapy involving the use of anesthesia or anesthetic from a chiropractor.

## 5. Add Section 318.2(e).

This proposal would add section 318.2(e) to prohibit a chiropractor from directing, instructing, interfering, or making orders to the physician and surgeon or other health care provider who is administering and maintaining the anesthesia.

#### Add Section 318.2(f).

This proposal would add section 318.2(f) to clarify that ECSW therapy involving the use of anesthesia or anesthetic shall be performed by a licensed and competent doctor of chiropractic who shall formulate the ECSW therapy treatment plan and be

responsible for performing the ECSW therapy for that procedure. This section would further clarify that ECSW therapy is limited to ultrasound technologies within the scope of practice of a chiropractor.

## 7. Add Section 318.2(g).

This section would add section 318.2(g) to prohibit the chiropractor from being involved in or interfering with the physician and surgeon or other health care provider in the discharge of the patient following the ECSW therapy procedure.

# 8. Add Section 318.2(h).

This section would add section 318.2(h) to establish a failure by the chiropractor to follow the standard of care contained in this proposal when performing ECSW therapy involving the use of anesthesia or anesthetic as unprofessional conduct.

# 9. Add Section 318.2(i).

This section would add section 318.2(i) to define ECSW involving the use of anesthesia or anesthetic as an ultrasound based technology used to break up fibrotic scar tissues or calcifications within musculoskeletal soft tissues of a patient who is sedated by the administration of anesthesia by a physician and surgeon or other health care provider who is legally authorized to administer anesthesia.

#### 10. Add Section 318.2(j).

This section would add section 318.2(j) to clarify that nothing in this proposal shall be construed to authorize a licensed doctor of chiropractic to perform an ablative procedure.

#### POLICY STATEMENT OVERVIEW/ANTICIPATED BENEFITS OF PROPOSAL

The health and safety of chiropractic patients will be strengthened through this proposal by setting a standard of care for the ECSW therapy involving the use of anesthesia or anesthetic to ensure that the health care practitioners providing the therapy and anesthesia are providing treatment within their scope of practice and for which they have been properly trained. Additionally, this proposal will enhance the Board's enforcement authority to discipline licensees who fail to comply with this proposal.

## CONSISTENCY AND COMPATIBILITY WITH EXISTING STATE REGULATIONS

The Board has evaluated this regulatory proposal and it is not inconsistent nor incompatible with existing state regulations.

#### FISCAL IMPACT ESTIMATES

<u>Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State:</u> None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for which Government Code Sections 17630 Require Reimbursement: None

#### Business Impact:

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

# Cost Impact on Representative Private Person or Business:

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

#### Effect on Small Business:

The Board has determined that this regulatory proposal would not have an adverse effect on small businesses. Although chiropractic offices are considered a small business, this proposal will not impose any fiscal effect upon them. This proposal would simply set a standard of care for chiropractors who offer ECSW therapy under anesthesia for the safety of their patients.

# RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS

# Impact on Jobs/Businesses:

The Board has determined that this regulatory proposal will not have any impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

# **Benefits of Regulations:**

The health and safety of chiropractic patients will be strengthened through a standard of care for the provision of ECSW therapy involving the use of anesthesia

or anesthetic through a clear definition of the roles in which the licensed doctor of chiropractic and physician and surgeon or other health care provider legally authorized to administer anesthesia must adhere to when providing this therapy. This proposal will also define the technologies which are appropriate for this therapy, which would prohibit a licensed doctor of chiropractic from using technology outside of the chiropractic scope of practice.

## **CONSIDERATION OF ALTERNATIVES**

The Board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements in writing relevant to the above determinations to the address provided above.

## INITIAL STATEMENT OF REASONS AND INFORMATION

The Board has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

#### **TEXT OF PROPOSAL**

Copies of the exact language of the proposed regulations, the initial statement of reasons, and all the information, upon which the proposal is based, may be obtained upon written request from:

Dixie Van Allen, Program Analyst 2525 Natomas Park Drive, Suite 260 Sacramento, California 95833 (916) 263-5329 Fax (916) 263-5369 dixie.vanallen@CHIRO.ca.gov

# AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file that is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the web site, **www.chiro.ca.gov.** 

## CONTACT PERSON

Inquiries concerning the proposed administrative action may be directed to:

Name: Dixie Van Allen, Program Analyst Address: 2525 Natomas Park Drive, Suite 260

Sacramento, California 95833

Telephone: (916) 263-5329 Fax (916) 263-5369

E-mail: dixie.vanallen@CHIRO.ca.gov

## The backup contact person is:

Name: Robert Puleo

Address: 2525 Natomas Park Drive, Suite 260

Sacramento, CA 95833

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E-mail: chiro.info@chiro.ca.gov

Web Site Address: Materials regarding this proposal can be found at www.chiro.ca.gov.